

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A process for the sterile packaging of a prosthetic implant made of polyethylene, including the steps of successively placing the implant in a flexible, gas-impermeable sachet having an opening adapted to be sealed, creating a vacuum in the sachet and then sealing its opening,

placing the sachet containing the implant in a gas-impermeable envelope including an opening adapted to be sealed,

establishing an inert gaseous atmosphere in the envelope, and thereafter closing the envelope hermetically by sealing its opening, and thereafter, sterilizing the implant within the sachet and the envelope by irradiation, wherein pressure of the inert gas in the envelope is greater than or equal to a pressure in the sachet.

2. (Previously presented) The process of Claim 1, wherein the closure of the sachet and of the envelope is effected by heat-sealing their respective openings.

3. (Original) The process of Claim 1, wherein the inert gaseous atmosphere formed in the envelope is constituted by argon, nitrogen or a mixture of these gaseous elements.

4. (Previously Presented) The process of Claim 1, wherein the sachet includes a layer of aluminium.

5. (Previously Presented) The process of Claim 1, wherein the envelope includes a layer of a polyamide and a layer of a polyethylene.

6. (Previously Presented) The process of Claim 1, wherein the step of establishing the inert gaseous atmosphere in the envelope includes:
creating a vacuum around and inside the envelope, and

injecting an inert gas inside the envelope until the pressure inside the envelope reaches a predetermined value less than atmospheric pressure,
and,

after having hermetically closed the envelope, the envelope is subjected to atmospheric pressure so that the inert gaseous atmosphere in the envelope has a pressure which is not less than the pressure in the sachet.

7. (Previously Presented) The process of Claim 6, wherein the inert gas is injected into the envelope until the pressure of the inert gaseous atmosphere in the envelope reaches a predetermined value between 0.3 and 0.7 bar.

8. (Previously Presented) The process of Claim 1, wherein, before or after irradiation of the implant, an assembly formed by the implant, the sachet and the envelope is placed in a rigid packing whose internal volume is substantially equal to the volume occupied by the assembly.

9. (Original) The process of Claim 8, wherein, before placing the assembly formed by the implant, the sachet and the envelope in the rigid packing, the envelope is folded on itself.

10. (Previously Presented) The process of Claim 8, wherein the rigid packing and the envelope cooperate by being of complementary shapes in order to immobilize the sachet containing the implant.

11. (New) A process for the sterile packaging of a prosthetic implant that includes polyethylene, the process comprising the steps of:

sealing the prosthetic implant in a flexible, gas-impermeable sachet at a first pressure;

locating the sachet containing the prosthetic implant in a gas-impermeable envelope, the envelope including an opening adapted to be sealed;

establishing an inert gaseous atmosphere in the envelope;

hermetically sealing the opening so that the inert gaseous atmosphere in the envelope comprise a second pressure greater than or equal to the first pressure in the sachet; and

sterilizing the implant within the sachet and the envelope by irradiation.

12. (New) The process of claim 11 comprising selecting a sachet that includes a layer of aluminium.

13. (New) The process of claim 11 comprising selecting a sachet that is opaque to visible light.

14. (New) The process of claim 11 wherein the step of sealing the sachet comprises the steps of:

reducing a pressure in and around the sachet containing the prosthetic implant to about the first pressure; and
sealing the sachet.

15. (New) The process of claim 11 wherein the step of sealing the sachet comprises the steps of:

evacuating the envelope containing the sachet and the prosthetic implant;
introducing an inert gas into the envelope at about the second pressure; and
sealing the envelope.

16. (New) The process of claim 11 wherein the inert gaseous atmosphere comprises argon, nitrogen, or a mixture thereof.

17. (New) The process of claim 11 wherein the envelope comprises a layer of a polyamide and a layer of a polyethylene.

18. (New) The process of claim 11 wherein the envelope comprises a rigid or semi-rigid material.

19. (New) The process of claim 11 wherein the step of establishing the inert gaseous atmosphere in the envelope comprises injecting an inert gas inside the envelope until the pressure inside the envelope reaches about the second pressure.

20. (New) The process of claim 11 wherein the second pressure comprises a pressure less than atmospheric pressure.

21. (New) The process of claim 11 wherein the second pressure comprises a pressure of about 0.3 to about 0.7 bar.

22. (New) The process of claim 11 comprising the step of locating an assembly comprising the envelope containing the sachet and prosthetic implant in a rigid container comprising an internal volume substantially equal to a volume occupied by the assembly.

23. (New) The process of claim 11 comprising the step of locating an assembly comprising the envelope containing the sachet and prosthetic implant in a rigid container comprising an internal shape complementary to a shape of the assembly.

24. (New) A process for the sterile packaging of a prosthetic implant that includes polyethylene, the process comprising the steps of:

locating the prosthetic implant in a flexible, gas-impermeable sachet;

locating the sachet containing the prosthetic implant in a gas-impermeable envelope;

reducing a pressure in and around the sachet containing the prosthetic implant to about the first pressure;

sealing the sachet;

evacuating the envelope containing the sachet and the prosthetic implant;
introducing an inert gas into the envelope;
sealing the envelope so that the inert gaseous atmosphere in the envelope
comprises a second pressure greater than or equal to the first pressure in the sachet; and
sterilizing the envelope containing the implant within the sachet by irradiation.

25. (New) The process of claim 24 wherein the envelope comprises
a rigid or semi-rigid material.

26. (New) The process of claim 24 wherein the second pressure
comprises a pressure less than atmospheric pressure.

27. (New) The process of claim 24 wherein the second pressure
comprises about 0.3 and about 0.7 bar.

28. (New) A process for the sterile packaging of a prosthetic
implant that includes polyethylene, the prosthetic implant is sealed at a first pressure in a
flexible, gas-impermeable sachet, the process comprising the steps of:

locating the sachet containing the prosthetic implant in a gas-impermeable
envelope, the envelope including an opening adapted to be sealed;

establishing an inert gaseous atmosphere in the envelope;

hermetically sealing the opening so that the inert gaseous atmosphere in the
envelopes comprise a second pressure greater than or equal to the first pressure in the sachet;
and

sterilizing the implant within the sachet and the envelope by irradiation.

29. (New) The process of claim 28 wherein the envelope comprises
a rigid or semi-rigid material.

30. (New) The process of claim 28 wherein the step of establishing the inert gaseous atmosphere in the envelope comprises injecting an inert gas inside the envelope until the pressure inside the envelope reaches about the second pressure.

31. (New) The process of claim 28 wherein the second pressure comprises a pressure less than atmospheric pressure.

32. (New) The process of claim 28 wherein the second pressure comprises a pressure of about 0.3 to about 0.7 bar.

33. (New) The process of claim 28 comprising the step of locating an assembly comprising the envelope containing the sachet and prosthetic implant in a rigid container comprising an internal volume substantially equal to a volume occupied by the assembly.

34. (New) The process of claim 28 comprising the step of locating an assembly comprising the envelope containing the sachet and prosthetic implant in a rigid container comprising an internal shape complementary to a shape of the assembly.